Patent
218/126

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

BENETTI, Federico J. et al.

Serial No. 08/603,328

Filed: February 20, 1996

For: SURGICAL DEVICES FOR IMPOSING A NEGATIVE PRESSURE TO FIX THE POSITION OF CARDIAC TISSUE DURING SURGERY

Group Art Unit 3309

Examiner Rasche, P.

AFFIDAVIT OF CHARLES S. TAYLOR PURSUANT TO 37 C.F.R. § 1.131

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

1. I am the co-inventor with Federico J. Benetti and Robert G. Matheny of United States Patent application Serial No. 08/603,328.

2. I am Vice President and Chief Technical Officer of CardioThoracic Systems, Inc., assignee of the present application. I have over ten years of experience in the design and development of medical devices, specifically surgical instruments, and have several issued U.S. patents and numerous patent applications pending.

3. As part of an attempt to design and develop instruments for use in minimally invasive cardiac surgery, I examined the procedures used to perform cardiac surgical procedures

while allowing the heart to continue beating. I discovered that surgeons performed these procedures using conventional surgical instruments and would sometimes place stitches in the heart using sutures, followed by drawing tension on the sutures, to restrict the motion of the tissue. Because of the drawbacks in this approach, I focused on creating a special surgical instrument that would use negative pressure (suction) applied to the beating heart in contact with the instrument.

4. I have reviewed the Borst et al. PCT patent application submitted to the PTO in relation to my application.

5. Prior to September 20, 1995, the filing date of the United States application of Borst et al., I constructed a suction-based device that could be applied to a portion of the beating heart using suction to restrict the motion of the cardiac tissue in contact with the device.

6. As part of an animal study in November 1994, I applied the instrument to a pig that had the beating heart exposed by median sternotomy and left thoracotomy. The conditions of the animal study were such that I tested the device using less volume of suction than would normally be available to a surgeon in an operating room. Specifically, I was using a small portable pump rather than the central suction system used in a hospital operating room. Furthermore, I had to be extremely careful not to damage the beating heart of the pig with excessive suction pressure during the animal study. For this reason, I did not exert a high suction pressure which might cause damage to the tissue of the beating heart.

a) During the study, with suction turned on, I applied the instrument to several locations on the surface of the beating heart.

b) I was able to selectively orient the instrument to cause each of the suction ports to attach to the surface of the beating heart. The motion of the cardiac tissue at the points of attachment to the instrument was eliminated and was substantially reduced in the immediately surrounding areas.

c) The device that I manufactured had a plurality of suction ports oriented in an array to apply negative pressure (i.e., suction) to the beating heart. In particular, the housing of the device had several bases with suction ports inside such that the opening of the ports were in the bottom surface of the housing. During the study, I contacted each base to the surface of the heart to apply negative pressure to several points on the surface of the heart. The negative pressure was communicated to each suction port via an inlet and a pneumatically sealed chamber within the housing.

7. The prime objective of the animal study was to determine whether an instrument applied to the beating heart with suction could effectively minimize the motion of a portion of tissue on the outside of the beating heart. Prior to the animal study, I had witnessed numerous cardiac surgeries using conventional instruments and techniques and had the ability to determine whether the amount of motion restriction achieved using the device tested would assist a surgeon attempting to operate on a beating heart.

8. I also concluded that certain modifications would be necessary before the device was perfected. The modifications were based on my observations as follows:

a) The suction ports were spaced too widely from one another.

b) The suction ports could become detached from the beating heart and the detachment of one suction port would lower the pressure in the others.

9. Each of these modifications could be achieved by a straight forward mechanical modification that was readily apparent.

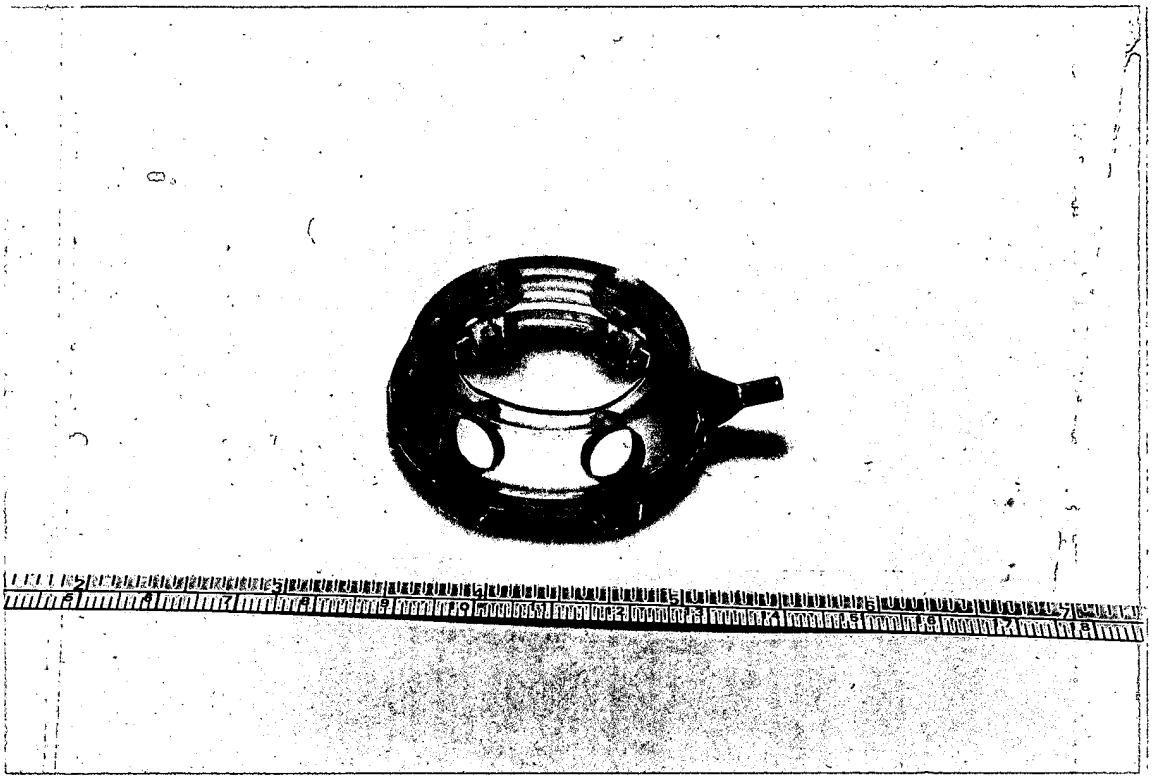
For example,

a) the suction ports could be moved closer together to provide improved motion restriction between the points where the instrument contacted the beating heart;

b) the device was already provided with a small diameter orifice between each port and the suction plenum so that the detachment of one suction port would not lower the suction pressure in the others. To provide a more effective attachment force, this design simply required a greater amount of suction then was available in the animal study.

I also knew that the diameter of the suction ports could be enlarged to provide a greater effective area and thus attachment force, and that the amount of suction that would be available to a user of a commercial embodiment of the device would be substantially greater because the user could employ the central suction source that is available in hospital operating rooms.

10. The device shown in the photograph immediately below is the same device tested in November 1994.



11. The documents attached hereto as Exhibits A and B were created by me personally and were obtained from my personal files.

a) Attached hereto as Exhibit A is a document entitled "Informal Animal Study #1" which I prepared on November 4, 1994 and which describes the results of the animal study.

b) Attached hereto as Exhibit B is a document labelled "'Turtle Shell' Device #1 used in 11-4-94 experiment" which is referred to in Exhibit A and which was prepared on November 3, 1994, was signed and dated on November 9, 1994, and was inserted into my personal lab notebook on November 11, 1994, and which reflects the overall design of the invention.

12. All of the activities described herein and reflected in the accompanying documents were conducted in this country.

13. I, the undersigned inventor, being hereby warned that wilful false statements made herein are punishable by fine or imprisonment or both under 18 U.S.C. 1001, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon, do hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true.

Date: 5-29-97

Charles S. Taylor